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I, JULIE BILLINGSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2002952938 for a patent by ILIFE PTY LIMITED as filed on 27 November 2002.

I further certify that the name of the applicant has been amended to ILIFEDATA PTY LTD pursuant to the provisions of Section 104 of the Patents Act 1990.

WITNESS my hand this
Eleventh day of December 2003

J. Billingsley

JULIE BILLINGSLEY
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ILIFEDATA PTY LTD

AUSTRALIA
Patents Act 1990

PROVISIONAL SPECIFICATION FOR THE INVENTION ENTITLED:

"SYSTEM FOR CONDUCTING CLINICAL TRIALS"

The invention is described in the following statement:-

SYSTEM FOR CONDUCTING CLINICAL TRIALS

The invention relates to a system for conducting clinical trials on people and, in particular, to a system for efficiently conducting clinical trials.

The invention has been developed primarily for use with the clinical trials of pharmaceutical substances and devices and methods of treatment and will be described hereinafter with reference to these applications. However, it will be appreciated that the invention is not limited to this particular field of use.

As part of the process of introducing pharmaceutical substances, devices or methods to treat viruses, diseases or other undesirable conditions in people, several layers of trial must be conducted to ensure that the ultimate end user of such a pharmaceutical, device or method receives not only a benefit from the pharmaceutical substance but also does not suffer from any undesirable side-effects.

Pharmaceutical substances, devices or methods of treatment are often tested on animals as an initial step to assess their effectiveness and also whether any undesirable side effects will accompany their use.

Once the testing on animals has been completed, the results of the test are reviewed and if the test results satisfy some predetermined conditions, then clinical trials of the pharmaceutical, device or method may be conducted on humans to further evaluate and possibly refine the device, method or pharmaceutical substance or its dosage.

As would be expected, the clinical trials on people must be conducted under procedures determined by local authorities, for example the Food and Drug Administration in the US and the Therapeutic Goods Administration in Australia.

As is commonly known in most countries, the regulatory requirements for having a pharmaceutical substance, device or method of treatment available to people generally requires rigorous testing and reporting procedures to be followed to satisfy local authorities and for the ultimate safety of the consumer. These required trials and reports are therefore

critical to the ultimate commercial success of the pharmaceutical product or device of method of treatment.

In the case of pharmaceutical substances, it is also commonly known that conducting clinical trials of on people is a long process at least due to the fact that unwanted side effects related to the pharmaceutical or a formulation may appear a substantial period of time after the pharmaceutical product was trialed. Similarly, the dosage level and rate and efficiency of the pharmaceutical substance in treating a condition generally also takes a significant period of time to assess. Similarly, in the case of devices such as implants or methods of treatment, any unwanted side effects may not appear for a substantial time.

Many different professionals or technicians are involved in such a clinical trial of the pharmaceutical substance, device or method of treatment and it has been found that information related to such a trial can be scattered over a variety of institutions or stored in a not easily accessible manner to those monitoring the trial, for example. This ultimately prolongs the trial process with the primary effect of incurring additional expense by keeping the pharmaceutical, device or method of treatment from the market.

An important aspect of the conduct of clinical trials of a pharmaceutical substance relates to its manufacture, distribution, consumption and disposal. Many known methods of conducting clinical trials do not have a pharmaceutical substance inventory monitoring capability which, in addition to creating difficulties for the trial workers to monitor the pharmaceutical substances, unnecessarily slows the overall progress of a clinical trial and makes accounting for all of the substance difficult. Similarly in the case of devices and methods of treatment, a lack of monitoring in known methods of conducting clinical trials disadvantageously provides difficulties in monitoring the devices and any equipment associated with the methods of treatment.

Furthermore, in the known methods of conducting clinical trials, relatively large volumes of printed matter relating to the trial are produced. It is known that the tracking of all of the printed matter is difficult and provides multiple access points for corrupt data to be included in the trial.

It is an object of the invention to provide a system for conducting clinical trials which will overcome or substantially ameliorate at least some of these deficiencies of the prior art or provide a useful alternative.

According to a first aspect of the invention there is provided a method of conducting a clinical trial of a device or method or substance of treatment on a plurality of trial participants, the method including the steps of:

establishing an electronic database in communication with one or more remote computers;

entering predetermined trial parameters of the conduct of the clinical trial into the database;

programming the database and remote computers to provide a predetermined interface for accepting predetermined information relating to the trial being entered by trial participants, administrators and/or auditors;

recording particulars of the trial participants and forming ordered registration information on the database;

forming randomized particulars of the trial participants in the database from the ordered registration information, the randomized particulars including the allocation of an identifier label;

assigning the device or method or substance of treatment to the randomised particulars of each trial participant;

entering trial data via the predetermined interface into the database by an authorized trial participant;

producing a report of data entered onto the database in response to predetermined reporting conditions;

controlling and tracking the ordering, allocation and dispensing of the method or substance of treatment and compiling a device or method or substance inventory record on the database; and

terminating the clinical trial in response to predetermined termination conditions.

In preferred embodiments, the method is for conducting a clinical trial of a pharmaceutical substance.

Preferably, the predetermined trial parameters include the dosage rates of the pharmaceutical substance to be given to the selected trial participants and wherein the trial data is entered onto the remote computer or the database and wherein only specific volumes and forms of the data are acceptable by the remote computer or database.

In preferred embodiments, the trial administrators have access to view any entered data or add any predetermined data to the information in the database, and the trial auditors have access to view any entered information in the database.

Preferably, the method includes the step of generating reminders from the database at predetermined times after trial data is entered, the reminders being displayed to predetermined trial participants upon access to the remote computers or the database.

In preferred embodiments, the trial report of entered data reports on all data entered into the database at a predetermined time or in response to the entry of specific data types or quantities. More preferably, the step of controlling and tracking the movement of the pharmaceutical substances and recording the pharmaceutical substance inventory record on the database further includes the step of selectively establishing communication with the pharmaceutical substance supplier and placing an electronic order.

Preferably, the trial termination conditions include a lapsing of a predetermined time, consumption of a predetermined amount of pharmaceutical substance by one or more trial participants, or the occurrence of an adverse event of a trial participant. More preferably, a plurality of pharmaceutical substances are simultaneously trialed and controlled by the database.

In preferred embodiments, the remote computers are selected from the group consisting of: personal digital assistants, laptop computers, desktop computers, tablet personal computers, mobile telephones, pagers and dedicated computing devices, and the remote computers and electronic database communicate by wireless, electrical cable and/or optical fibre networks. Also preferably, the electronic database includes a computer server in combination with a data storage device.

According to another aspect of the invention there is provided a system for conducting a clinical trial of a device or method or substance of treatment on a plurality of trial participants, the system including:

a database having a memory means in communication with a database means;

one or more trial sites each having a remote computer located remotely from the database and in communication therewith;

the database being configured to receive predetermined parameters of the trial;

both the database and the remote computers being configured to receive predetermined trial data from one or more trial participants; and

the database being configured to control and track the ordering, allocation and dispensing of the device or method or substance of treatment and compiling a device or method or substance inventory record on the database;

wherein the database being configured to terminate the clinical trial in response to one or more predetermined trial termination conditions.

In preferred embodiments, the system is for conducting a clinical trial of a pharmaceutical substance and the database is configured to receive and record information relating to the trial participants and also to form randomised particulars of the trial participants in the database including the determination of which trial participants receive the pharmaceutical substance and which receive a placebo.

Preferably, the database is configured to produce a report of data entered into the database relating to the trial and the database is configured to generate reminders to the trial administrators at a predetermined time after trial data is entered or the trial commenced, the reminders being displayed upon the trial administrators accessing a remote computer.

A preferred embodiment will now be described, by way of example only, with reference to the accompanying drawings in which:

Fig. 1 is a schematic view of a system in accordance with the embodiment.

Referring to the drawing, there is illustrated a system 1 of conducting a clinical trial of a pharmaceutical substance or device or method of treatment on a plurality of trial participants and the system 1 will be described with reference conducting a clinical trial of a

pharmaceutical substance. The trial participants are located over a plurality of study sites. However, in other embodiments not illustrated, the trial participants are located at one site.

An electronic database 2 is disposed at one location and a remote computer 3 in communication with the database 2 is disposed at each of the plurality of remote study sites. The remote computer 3 can be in the form of a personal digital assistant (PDA), laptop or other personal computer, mobile telephone or other device. The communication link between the remote computer 3 and the database 2 can communicate by any conventional cable or wireless communication means. It is also noted that the electronic database 2 can include any processor in combination with a memory means such as a computer server in combination with a data storage device or a plurality of processors and/or memory means or any other conventional database arrangement.

The parameters by which the clinical trial is to be conducted are entered into the database 2. These trial parameters or rules must comply with local regulations including the timing of the trial and definitions of functions of the remote trial sites as well as any dosage rates of the pharmaceutical substance being trialed.

Both of the database 2 and remote computers 3 are programmed to provide a predetermined interface to a user. In this interface, the database or remote computers will only accept predetermined information in a predetermined form to standardise data collection from trial participants and trial administrators. For example, dates relating to events in the clinical trial must be recorded in the format MM/DD/YY. Further, the interface to the database 2 and remote computers 3 is configured to accept identifying information and medical history of trial participants.

Once the total number of trial participants has been finalised, their personal particulars are entered onto the database and/or remote computers to an ordered registration information file. The information in the ordered registration information files is available to predetermined trial administrators and trial auditors and any other predetermined persons. It is noted that the trial auditors can be any relevant party including overseeing doctors or government bodies for example.

The database 2 then forms a randomised particulars file on the database 2 for each trial participant in the ordered registration information file. The randomised particulars files are formed once the ordered registration information files are created. However, in other embodiments, the randomised particulars files are selectively created in batches.

The randomised particulars file includes the allocation of a label for identifying the trial participant. Furthermore, the database 2 randomly selects which trial participants receive the pharmaceutical substance as part of the clinical trial and which trial participants receive a placebo. This information is recorded in only the ordered registration information files and only predetermined auditors, for example, can correlate the randomised particulars files with corresponding ordered registration information files. The allocation of the pharmaceutical can also be performed after the randomised parts files are generated, or as part of the process.

In the conduct of the clinical trial, data relating to each trial participant as well as any other information relevant to the assessment of the clinical trial is entered via the predetermined interface into the database 2 by either a trial participant or trial administrator. The data can be entered via remote computers 3 and communicated to the database 2. When a trial administrator enters data relating to a trial participant, it must be in a predetermined format, for example, a predetermined combination of alphanumeric characters in order to be accepted by the remote computers 3 or database 2.

The database 2 is configured to produce a report of trial activity at predetermined times from the commencement of the clinical trial. These reports can be used by the trial administrators to review the conduct of the trial as well as by auditors to ensure that correct procedures are being followed. Importantly, the reports can also include details of any adverse events including the trial. The reports can also be generated in response to a specific query by a trial administrator or trial auditor relating to a specific trial participant or participants or, for example, a report based on the total number of trial participants receiving a particular pharmaceutical substance dose rate. Therefore, reports including any predetermined information can be generated.

The reports are also generated in response to data entered into the database 2 meeting predetermined conditions such that a ruling or adjudication of the entered trial results needs to

occur. That is, entered data meeting predetermined conditions triggers a request for the trial administrators to adjudicate the results.

The database 2 also controls the allocation of the pharmaceutical substance being trialed to the trial participants. The database 2 orders a predetermined quantity of the pharmaceutical substance depending on the number of trial participants and their dosages. The database 2 monitors the use of the pharmaceutical substance from data entered during the trial and compares this information against anticipated pharmaceutical substance usage rates. A record of the pharmaceutical substance is maintained by the database 2 in a pharmaceutical substances inventory record.

Once the quantities of pharmaceutical substance for the trial participants reach a lower threshold level, the database 2 automatically establishes communication with the supplier 4 of the pharmaceutical substances and re-orders a predetermined quantity depending on the future needs of the trial.

The database 2 further monitors the trial data entered and terminates the trial in response to one or more predetermined termination conditions. The predetermined termination conditions include the elapsing of a predetermined time for the trial, the consumption of a predetermined amount of pharmaceutical substance by one or more of the trial participants, or the occurrence of an adverse event in a trial participant. Such adverse events include unpredicted side-effects or other illnesses. The database 2 can also terminate the trial in a number of trial participants or the trial as a whole.

The database 2 and the remote computers 3 communicate over the internet. The database 2 and computers 3 each include a modem for allowing communication between the database 2 and computers 3 to be achieved. In other embodiments of the invention not illustrated, the database 2 and computers 3 each include a network card for allowing dedicated communications therebetween. Similarly in the case of the database 2 establishing communication with the supplier of the pharmaceutical substance, the supplier 4 and database 2 communicate via a modem or dedicated network link. Alternatively, the database 2 and computer 3 can communicate by wireless means.

In respect of accessibility to the ordered registration information files containing information relating to each trial participant and data entered throughout the trial, only predetermined trial administrators and trial auditors can read the data and no person can erase or re-write data. The database 2 records a log of access to trial information, for example an ordered registration information file, primarily to avoid the possibility of the data being deleted or altered by unauthorised persons. In this way, the integrity of the data is maintained by not allowing a means of falsifying data.

However, the randomised particulars files are able to be read by trial administrators and auditors, but not trial participants. It is noted that the randomised particulars files do not identify the participant directly or whether they are consuming the pharmaceutical substance or placebo as part of the trial.

The system 1 also includes a reminder generator, not illustrated, integrated into the database 2. When data is entered into the database 2, it will trigger the generation of a reminder following up the data at a predetermined advance date. The advance date depends on the data entered, for example, when an ordered information file is created, a reminder is generated for one week hence to ensure that a corresponding randomised particulars file has also been created. Similarly, when an adverse event of a trial participant or participants is entered into the database 2, a reminder is automatically generated for an advance date to follow up the entry of the adverse event. However, the system 1 can be configured to generate any other required reminders, for example, based on an elapsed time or the occurrence of a predetermined event.

It is also noted that the system 1 can be used to trial more than one pharmaceutical substance simultaneously. For example, the trial parameters can be predefined to include a trial of an additional pharmaceutical substance.

Likewise, the system 1 can be used to trial one pharmaceutical substance, however, variants or different formulations of the substance can also be simultaneously trialed within the one trial. The variants of a pharmaceutical substance can include biochemical variants or variants in physical state such as liquid or tablet. For example, some participants in a pharmaceutical substance trial can be given a liquid form of the substance, other participants given a tablet

form of the substance and yet other participants given biochemically varied forms of the substance in either liquid or tablet form.

The database 2 and remote computers 3 are also configured to selectively access information relating to the trial via the internet. For example, the database 2 and remote computers 3 can access the local regulatory framework for conducting the trials.

It will be appreciated that although the foregoing describes a preferred embodiment of he invention relating to a method and system for conducting clinical trials of a pharmaceutical substance, it will be appreciated that the method and system are equally applicable to the conduct of clinical trials of devices or methods of treatment or surgical techniques, for example. That is, the foregoing describes only a preferred embodiment of the present invention and modifications, obvious to those skilled in the art, can be made thereto without departing from the scope of the present invention.

ASPECTS OF THE INVENTION

The following paragraphs define some aspects of the present invention:

1. A method of conducting a clinical trial of a device or method or substance of treatment on a plurality of trial participants, the method including the steps of:

establishing an electronic database in communication with one or more remote computers;

entering predetermined trial parameters of the conduct of the clinical trial into the database;

programming the database and remote computers to provide a predetermined interface for accepting predetermined information relating to the trial being entered by trial participants, administrators and/or auditors;

recording particulars of the trial participants and forming ordered registration information on the database;

forming randomized particulars of the trial participants in the database from the ordered registration information, the randomized particulars including the allocation of an identifier label;

assigning the device or method or substance of treatment to the randomised particulars of each trial participant;

entering trial data via the predetermined interface into the database by an authorized trial participant;

producing a report of data entered onto the database in response to predetermined reporting conditions;

controlling and tracking the ordering, allocation and dispensing of the device or method or substance of treatment and compiling a method or substance inventory record on the database; and

terminating the clinical trial in response to predetermined termination conditions.

2. A method as defined in paragraph 1 wherein the method is for conducting a clinical trial of a pharmaceutical substance.

3. A method as defined in paragraphs 1 or 2 wherein the database and remote computers communicate via internet communications.

4. A method as defined in paragraphs 2 or 3 wherein the predetermined trial parameters include the dosage rates of the pharmaceutical substance to be given to the selected trial participants.

5. A method as defined in any one of the preceding paragraphs wherein the trial data is entered onto the remote computer or the database and wherein only specific volumes and forms of the data are acceptable by the remote computer or central database.

6. A method as defined in any one of paragraphs 1 to 5 wherein the trial administrators have access to view any entered data or add any predetermined data to the information in the database, and the trial auditors have access to view any entered information in the database.

7. A method as defined in any one of paragraphs 1 to 6 wherein the recorded particulars of the selected participants in the ordered registration information are restricted to predetermined trial administrators and auditors.

8. A method as defined in any one of paragraphs 1 to 7 wherein the randomized particulars of the selected trial participants and trial information relating to those participants are available to all trial participants.

9. A method as defined in any one of paragraphs 1 to 8 including the step of generating reminders from the database at predetermined times after trial data is entered, the reminders being displayed to predetermined trial participants upon access to the remote computers or the database.

10. A method as defined in any one of paragraphs 1 to 9 wherein the trial report of entered data reports on all data entered into the database at a predetermined time or in response to the entry of specific data types or quantities.

11. A method as defined in any one of claims 2 to 10 wherein the step of controlling and tracking the movement of the pharmaceutical substances and recording the pharmaceutical substance inventory record on the database further includes the step of selectively establishing communication with the pharmaceutical substance supplier and placing an electronic order.

12. A method as defined in any one of paragraphs 2 to 11 wherein the trial termination conditions include a lapsing of a predetermined time, consumption of a predetermined amount of pharmaceutical substance by one or more trial participants, or the occurrence of an adverse event of a trial participant.

13. A method as defined in any one of the preceding paragraphs including a plurality of remote computers each being disposed at individual sites remote from the database and being configured to accepted on predetermined data.

14. A method as defined in any one of paragraphs 2 to 13 wherein a plurality of pharmaceutical substances are simultaneously trialed and controlled by the database.

15. A method as defined in any one of the preceding paragraphs wherein the remote computers are selected from the group consisting of: personal digital assistants, laptop computers, desktop computers, tablet personal computers, mobile telephones, pagers and dedicated computing devices.

16. A method as defined in any one of the preceding paragraphs wherein the remote computers and electronic database communicate by wireless, electrical cable and/or optical fibre networks.

17. A method as defined in any one of the preceding paragraphs wherein the electronic database includes a computer server in combination with a data storage device.

18. A system for conducting a clinical trial of a device or method or substance of treatment on a plurality of trial participants, the system including:

a database having a memory means in communication with a database means;

one or more trial sites each having a remote computer located remotely from the database and in communication therewith;

the database being configured to receive predetermined parameters of the trial;

both the database and the remote computers being configured to receive predetermined trial data from one or more trial participants; and

the database being configured to control and track the ordering, allocation and dispensing of the device or method or substance of treatment and compiling a device or method or substance inventory record on the central database;

wherein the database being configured to terminate the clinical trial in response to one or more predetermined trial termination conditions.

19. A system as defined in paragraph 18 wherein the system is for conducting a clinical trial of a pharmaceutical substance.

20. A system as defined in paragraph 19 wherein the database is configured to receive and record information relating to the trial participants and also to form randomised particulars of the trial participants in the database including the

determination of which trial participants receive the pharmaceutical substance and which receive a placebo.

21. A system as defined in any one of paragraphs 18 to 20 wherein the database is configured to produce a report of data entered into the database relating to the trial.

22. A system as defined in any one of paragraphs 18 to 21 wherein the database is configured to generate reminders to the trial administrators at a predetermined time after trial data is entered or the trial commenced, the reminders being displayed upon the trial administrators accessing a remote computer.

23. A system as defined in any one of paragraphs 18 to 22 wherein the remote computers are selected from the group consisting of: personal digital assistants, laptop computers, desktop computers, tablet personal computers, mobile telephones, pages and dedicated computing devices.

24. A system as defined in any one of paragraphs 18 to 23 wherein the remote computers and database communicate by wireless, electrical cable and/or optical fibre networks.

25. A system as defined in any one of paragraphs 18 to 24 wherein the database includes a computer server in combination with a data storage device.

26. A method for conducting a clinical trial of a method or substance of treatment on a plurality of trial participants, the method being substantially as herein described with reference to the accompanying drawings.

27. A system for conducting a clinical trial of a method or substance of treatment on a plurality of trial participants, the system being substantially as herein described with reference to the accompanying drawings.

Dated this 27th Day of November, 2002

ILIFEDATA PTY LTD
By:

HODGKINSON OLD McINNES
Patent Attorneys for the Applicant

ABSTRACT

There is disclosed a system 1 for conducting a clinical trial of a pharmaceutical substance on a plurality of trial participants. The system 1 includes a central database 2 having a memory means in communication with a database means, one or more trial sites each having a remote computer 3 located remotely from the central database 2 and in communication therewith, the central database 2 being configured to receive predetermined parameters of the trial, both the central database 2 and the remote computers 3 being configured to receive predetermined trial data from one or more trial participants, the central database 2 being configured to control and track the ordering, allocation and dispensing of the pharmaceutical substances and compiling a pharmaceutical substance inventory record on the central database, and the central database 2 being configured to terminate the clinical trial in response to one or more predetermined trial termination conditions. A method of conducting a clinical trial of a pharmaceutical substance on a plurality of trial participants is also disclosed.

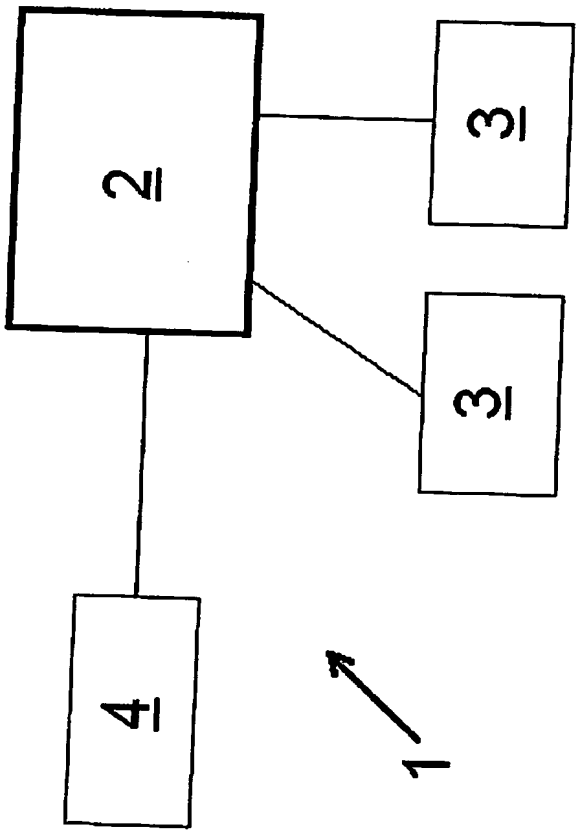

Fig. 1